

IV. Conclusion:

I have evaluated a representative sampling of claims alleging nonmalignant asbestos related disease filed under agreements providing financial incentive for the presence of impairment as defined within the contractual terms of the Agreements.

Determination of impairment was based upon results of pulmonary function testing performed in compliance with American Thoracic Society standards and the terms of the Agreements. Diagnosis of impairment was also predicated upon the finding of underlying asbestos related pleural disease or asbestosis (1/0 or greater). Furthermore, the diagnostic criteria for impairment were tied to the degree of underlying radiographic findings such that a premium was placed on the diagnosis of asbestosis over pleural disease.

The cases represented a snapshot of claims filed in the 1990s (predominantly 1994-1999). They represented a wide range of occupations and industrial settings for exposure. While exposures were difficult to identify in some cases, it appears the earliest first exposure was in 1925 and the latest first exposure in 1974. Length of exposure varied from 2-50 years.

Exposures were reported from the decades of the 20s, 30s, 40s, 50s, 60s & 70s.

After thorough review of 1691 claims randomly selected from 22,578 claims submitted for compensation for nonmalignant asbestos related disease under Agreements providing financial compensation for impairment, it is my opinion:

A) Impairment

- 1) 13.3% of cases qualified as impaired
- 2) Upward pressure on the number of impaired 13.3%
 - a) An additional 106 cases fulfilled the numerical values required for impairment compensation but materially failed to meet terms of the "Agreement" or ATS performance criteria and were felt to be deficient. There is reasonable question that some of this group could be impaired if retested.

- b) In 282 cases no PFT was performed or no tracings were submitted. Assuming a 7% incidence of impairment an additional 20 cases could occur.

3) Downward pressure on the number of impaired (13.3%)

- a) The number of impaired nonmalignant cases is dependent on the strength of the diagnosis of underlying nonmalignant asbestos disease. In this cohort, the following were felt to have significant impact in potentially further reducing the number of impaired nonmalignant cases.
 - 1) reliability of ILO and x-ray interpretation
 - 2) exposure history
 - 3) exclusion of other more probable cause
- b) Adherence to applicable ATS performance criteria including factors affecting predicted values

B) Diagnosis of nonmalignant disease

- 1) Over 80% of the claims in this cohort resulted from 5 "B" readers.
- 2) Observation of these "B" readers' patterns of interpretation, variance from peer review literature and greater than anticipated inter-reader variability have been discussed.
- 3) As there is substantial doubt about the reliability of certain of the x-ray interpretations, if these x-rays were reviewed by a randomly selected panel of reliable "B" readers, it is probable that the number of claims would be substantially reduced.
- 4) Quality control measures for x-ray review in the future would help address these issues.

C) Estimate of Impairment Attributable to Asbestos

An estimate of the incidence of impaired claims which might be attributable to asbestos in this cohort is between 8.2% and 10.5% of claims submitted. If one were to allow an additional 7% of the 282 claims without PFTs, this would add an additional 20 cases. If this were added to the 177 impaired (including deficiencies), this would result in 197 cases attributable to asbestos or 11.65% of the total cohort.

Thus it is unlikely that the 13.3% rate of impairment is likely to be significantly exceeded as the downward pressure on that number exceeds the upward pressure.

The recent surge in claims for nonmalignant asbestos disease cannot be fully explained on medical epidemiologic, pathologic or other scientific grounds. A distinction must be made between asbestos cases and nonmalignant asbestos claims. 20 years ago (1982) Walker made this distinction between the "minimally ill" and the "genuinely ill".

It is not advisable to base the determination as to whether or not a claimant qualifies for impairment solely on the basis of numerical values provided on PFTs. Careful analysis of the underlying PFT must be done to be certain that ATS acceptability and reproducibility standards are met. The "Agreement" with Appendix A and Appendix B appears well drafted to address this issue.

In certain pulmonary function laboratories, "systemic" issues were found which repeatedly affected numerous studies. Many times these issues were complex, their cause not readily apparent and further investigation was required. It is unlikely that such problems will be readily detected by non-medical reviewers. Many will go undetected when only a few studies are examined.

Significant questions are raised concerning interpretations by a minority of "B" readers. Unfortunately, these individuals accounted for over 80% of the x-ray reports responsible for the nonmalignant claims. Quality control measures providing for future review or audit of x-rays would help address this issue.

The single greatest factor which may determine the future number of impaired nonmalignant claims rests largely on the willingness of all parties to provide for ongoing review of the claims and underlying data including x-rays and PFTs. Adherence to ATS standards (including predicted values) will likewise play a major

role in determining the number of future impaireds. Finally, documentation of occupation and duration of exposure merit careful attention as does exclusion of nonasbestos related occupational and nonoccupational illness and injury as other more probable cause.

This study represents a "snapshot" of claims filed predominantly between 1994 and 1999. The actual impaired cases represent only a fraction of claims. Future impaired claims (2000-2049) should further decline if proper medical guidelines are enforced.

This report is submitted to Dr. Thomas Vasquez for his review and statistical analysis of the data to determine its reliability.

Respectfully submitted,

Gary K. Friedman, MD
GKF/df

APPENDIX 1

Methodology:

22,578 asbestos claims were identified which had been submitted to the National Settlement Program (NSP) under agreements which provided financial incentive for diagnosis of impairment.

Dr. Thomas Vasquez determined the cohort size necessary to provide an adequate number of cases to yield an appropriate sampling rate. Dr. Vasquez performed a stratified random sample involving 12 stratifications with proportional sampling involving industry/occupation and year of birth(Exhibit #2).

A total of 1691 charts were submitted for review (Exhibit #3). I had no involvement in the selection of cases. The claims were submitted by numerous different plaintiff firms from various geographic locations. The identity of all plaintiff firms was redacted from all documents and represented by an assigned code. I was blinded as to the identity of the law firms.

Method of Review:

My staff under my supervision identified all cases which lacked PFTs and entered these as unimpaired and deficient. I personally reviewed all cases where PFTs were present and determined presence or absence of deficiencies and whether or not claimant qualified for impairment. My staff entered ILO data under my supervision. All information was entered into an Access database.

The data was then analyzed by applying "filters" in the relational database. It was rechecked on multiple occasions for accuracy.

I) Demographics:

- A) Claimant name
- B) ID Number (NSP)
- C) Age
- D) Code for law firm submitting claim

2) X-ray data*

- A) ILO rating
- B) Presence or absence of pleural disease
 - 1) Unilateral (U)
 - 2) Bilateral (X) (often lacked C.P. angle)
 - 3) Fails to meet NSP pleural criteria such as category A1 or undefined pleural (?)

***No x-rays were reviewed by this physician and all ILO interpretations were recorded as reported by the plaintiff expert**

3) Pulmonary Function data

A) Impairment - defined according to criteria contained in the NSP agreement (Appendix A&B) and the operative American Thoracic Society Standards referenced in the NSP Agreement and Appendix A (Exhibit #6)

B) 1) Unimpaired - failure to substantially meet impairment criteria or failure to provide a pulmonary function test result

2) Unimpaired - Special Consideration

If the results of the tests were only contained in a narrative by Dr. Mitchell and there was no accompanying tracing to assess the accuracy of the study, the case was deemed unimpaired. The decision was made concerning the Mitchell cases based upon:
a) experience in reviewing tracings which accompanied other Mitchell reports in this study, b) most Mitchell reports failed to identify an FEV1/FVC ratio and thus, did not conform to criteria in the Agreement. In cases where pulmonary function test tracings accompanied the Mitchell report, they were judged as if submitted by any other physician.

C) Deficient - claim was based on a PFT which was not in compliance with the ATS criteria or the terms of Appendix A or Appendix B.

and the deficiency was sufficient to affect the interpretation or ultimate outcome of the study. Examples of deficiency included items marked by asterisks (*):

- 1) *Failure to provide flow volume loops or flow volume curves so that numerical values could not be verified and determination could not be made as to whether or not ATS acceptability criteria achieved.
- 2) *only one tracing or only one effort was submitted such that determination could not be made as to whether or not ATS reproducibility criteria had been achieved

Reproducibility - definition

- a) the ATS standard requires the best FVC and second best FVC to be within 5% of each other. The Appendix B of the NSP Agreement requires they be within 7%. As the latter was arrived at by agreement and favors the claimant, I utilized 7% or 200 cc (whichever was greater) to assess reproducibility.
- b) similar parameters were used for the FEV 1.

3)* Back extrapolation

4)* Error in Predicted Values

- A) Height
- B) BTPS
- C) Race - examples are cited but not quantified and are not reflected in the final analysis

5)* Selection of tracings which did not meet ATS definition of "best test"

Other data entered included:

D) FEV 1/FVC ratio

E) Lab

***F) 3 Test** - to identify deficiencies where 3 acceptable tests had not been submitted - deficient if at least 2 acceptable tests not presented.

***G) Exhale 5.4 sec** - to identify deficiencies where the claimant failed to exhale for 5.4 seconds per the contractual terms of the agreement. In this case the ATS agreement requires a 6 second exhalation time. I elected to give the contractual criteria precedence as it favors the claimant.

H) FVC - forced vital capacity

***I) TLC** - total lung capacity

***J) DLCO** - diffusion capacity - identifies cases in which DLCO played a significant role in determining presence or absence of disability or resulted in a deficiency. Causes of DLCO deficiency included:

1) Breath hold time (BHT) less than 9 or greater than 11 seconds

2) Failure to have 2 acceptable studies

3) IVC less than 90% of FVC

4) Failure to have 2 best studies within 90% of their average.

4) Additional information which was recorded included:

A) Date of first alleged exposure to asbestos (often difficult to

determine from limited exposure history provided)

- B) **Total exposure years** - usually very difficult to accurately quantify based on limited exposure history provided
 - C) **Occupation** (not on spread sheet - this is provided in exhibits) identifying samples of the diversity of job descriptions and industrial sites
- 5) **Comments** - allows for limited free form comments and miscellaneous

APPENDIX 2

Significant or Unusual Problems and Pulmonary Function Testing:

The following are provided solely as examples of issues that appeared to possibly related to the policies and procedures of a laboratory and thus might be expected to affect a substantial number of claims or impact future claims.

1) Patient Effort and Exhalation Time:

This was an unusually common finding at **Pulmonary Testing Services, Inc.** of Pascagoula, Mississippi. This laboratory was used Dr. Larry Mitchell of Petal, Mississippi. Exhalation time frequently failed to reach 5.4 seconds and was often less than 4 seconds (Exhibit #13 - a few representative samples). Another finding of this laboratory was **failure to administer bronchodilators** and retest when obstruction was present (Exhibit #14). Back extrapolation was also a common problem (Exhibit #14). Several plaintiffs were later **retested** by plaintiffs counsel at different laboratories with marked improvement in PFT results **changing status from impaired to nonimpaired** (Exhibit #15). Also Pulmonary Testing Services failed to provide documentation of **3 acceptable efforts** in most cases (Exhibit #14 is example). Reports from Pulmonary Testing Services appear to be most prolific in 1994 and early 1995 and then suddenly cease.

PTS listed all 3 efforts on May 2, 1995 (Exhibit #20). This represents a change in format from January 18, 1995 (Exhibit #14) when only 1 effort was reported but appears very similar in format to the "No Name" Lab used by Dr. H early in 1996 (or possibly earlier).

2) Shortly after the cessation of activity by Pulmonary Testing Services - a new PFT lab was observed which was not previously noted. A physician frequently ordering studies was Dr. H. The PFT reports bear **no identity** of the PFT lab. The reporting format appears similar to that previously used by Pulmonary Testing Services Inc. with the letterhead removed. In addition, some of the technicians have the same last name (Colgan Exhibit #16). As example, note similarity of Carl Taylor (Exhibit #16) with Festus Reed (Exhibit #15). This lab likewise had problems with **patient effort**. When retested at other laboratories at plaintiff request, certain claimants' PFT results improved significantly (Exhibit #16) (Exhibit #18) **changing claimant status from**

impaired to unimpaired. Questions concerning predicted values utilized by these laboratories are also raised.

In addition, this laboratory had certain unique issues in performance of the Total Lung Capacity (TLC) test. Despite many cases with severe obstruction in no case could I find hyperinflation ($\geq 120\%$) of predicted. The lung volumes are represented by trial one, trial two and trial three. This is followed by the word, AVG (average). In many of the cases reviewed, the AVG is greater than and does not equal to the AVG of the slow vital capacities. In addition the total lung capacity or TLC should equal the inspiratory capacity (IC) plus the functional residual capacity (FRC) ($IC + FRC = TLC$). Or in the alternative, $RV + VC = TLC$. Or $RV + VC$ should $= IC + FRC$ (See Glossary). In many cases I could not find where these equations balanced.

In the majority of cases, tracings were not provided to document how RV or FRC or TLC was actually measured.

Because of these observations, a partial audit was performed on the studies coming from Pulmonary Testing Services Inc. and "No Name" Lab (HLab). Even in cases where severe airway obstruction was present, I could find no instance where TLC exceeded 110% of predicted. The overwhelming majority of TLCs reported were less than 90% of predicted with many being less than 80%. These were 1/0 or 1/1 cases. In some cases (Exhibit #18) such as R.M. Marchant, the individual was only 40 years old, had a normal FVC (91%) with only 4 second exhalation and variable effort, airway obstruction and a TLC reported at 78%. This is nonphysiologic and there was no supporting evidence provided to show how the test was performed.

Because in most cases data was not available to show how the TLC was derived, lower than expected TLCs were reported, and the average values reported did not reflect an average of the actual test values, I elected to rely only on the spirometry values coming from these laboratories. If the spirometry did not deem an individual impaired, qualification for impairment was not granted solely on the basis of TLC for the reasons outlined above.

Attempts to call Pulmonary Testing Services in Pascagoula, Mississippi indicated no telephone number for that entity. The "No Name" lab did not have any identification as to phone number, address, etc., and thus could not be contacted.

The contribution of these 2 labs to the total cases with PFTs was substantial. PTS had

58 cases (Exhibit #22) which were identified. The "No Name" lab had at least 141 (Exhibit #23) for a total of 199. It is believed that this underestimates the number of PFTs performed by these 2 laboratories. Many of Dr. Mitchell's reports were not accompanied by PFT tracings and thus the lab could not be identified. The "No Name" lab carried no identification and thus could not always be identified. Cases were only ascribed to it when the format was as described and Dr. H was the ordering physician.

Health Screen Inc. Jackson, Mississippi

The following problems were noted with Health Screen, Inc.

- 1) **Best Test**-for reasons which are unclear, the "best test for FVC and FEV 1" as reported by Health Screen Inc frequently appears to not represent the best test which has been actually measured on the claimant. The American Thoracic Society indicates that "best test" means the highest values for FVC and FEV1 which are obtained (Exhibit #25). I inspected the flow volume loops and curves in a number of cases where it appeared that the best test was not reported. In some instances, the discrepancies are quite large. By example, in patient Terry Hoagland, the best test performed was test #4 with an FVC at 2.76 liters and FEV1 of 2.00 liters. For reasons which are unclear, the best test reported was 2.12 liters (FVC), with FEV1 of 1.67 liters. In the case of Mr. Billy Woodward, the best FVC obtained was 3.17 liters with an FEV1 of 2.63. However, the FVC that was reported as best test was 2.76 with an FEV1 of 2.11. In the case of Charles Roberts, the best FVC was 4.65 liters with an FEV1 of 2.94 (test three). However, the best test reported was that of 3.57 liters with an FEV1 of 2.15. This represents more than a one liter discrepancy. Careful inspection of the curves and flow volume loops show that the 4.65 liter test was well performed according to ATS standard. (Exhibit #24).
- 2) **BTPS** - wide variations of temperature and barometric pressure are noted. During the summer months and presumably in an indoor climate controlled environment, temperatures as low as 14° C and as high as 28° C are reported. Barometric pressure as high as P-Bar 782 and as low as 738 are observed. The ATS (Exhibits #10, #11) standard indicates that even lesser changes in barometric pressure and temperature may affect results by 10%. Furthermore, testing should not occur below 17° C. The wide variations which may occur within a given date are worrisome. By

example, on July 2, 1999, James W. Foster was reported to be tested at a temperature of 24° C and a barometric pressure of 764, Louis Thompson was tested at a temperature of 17° C and a barometric pressure of 757 and Terry Hoagland was tested at a temperature of 19° C and a barometric pressure of 745 (see enclosed examples) (Exhibit #26).

- 3) **Use of Appropriate Predicted Values** - Predicted values are predicated upon accurate determination of age, race (ethnicity), height and sex. The ATS standard (Exhibit #11), as identified in the Agreement Appendix A, the AMA (American Medical Association) Guide to Impairment and the recent ATS Pulmonary Function Laboratory Management and Procedure Manual (1998) (Exhibit #27) all support this position.

Health Screen Inc. identifies age, race, height and sex on their pulmonary function studies. When the resulting predicted values were checked against Morris, Intermountain Thoracic Society, Crapo and others, it was noted that the predicted values as published on the Health Screen Inc Pulmonary Function reports were not consistent with the anticipated predicted values. Further investigation revealed that discrepancies were predominantly noted with Black claimants.

To clarify this issue, I contacted Health Screen Inc. and spoke with the technician who could not provide answers. On a prior occasion, I had spoken with the Medical Director of Health Screen Inc. I was informed that the Medical Director is a PhD, not an MD. In my conversations with Health Screen Inc. and subsequent investigation, I developed significant concerns in regard to Health Screen Inc. interpretation of the ATS standards and the ATS PFT lab manual on this issue (Exhibit #11, Exhibit #27).

I obtained a copy of the pulmonary function lab manual from the ATS for purposes of documentation.

It was represented that the PFT equipment utilized by Health Screen Inc used software which did not correct for ethnicity. I learned the equipment utilized was made by

Spirometrix of Yerba Buena, CA (1-800-231-2466) and was model V-Max 22. I called Spirometrix and spoke with Mr. Kevin Clair who stated that the V-Max 22 in fact did correct for ethnicity- providing a 15% correction.

I contacted the manufacturer a second time and in further discussion with Spirometrix learned that the more recent model of the VMax 22 automatically adjusts for ethnicity (Knudson-Cotton Dust Standard and Hankinson -NHANES) whereas other predicted values may or may not adjust for ethnicity.

In a prior communication concerning this issue, the medical director had cited Dr. John Hankinson. Her position was Dr. Hankinson's predicted values disregarded ethnicity. I re-reviewed Hankinson, J.L., et al, Spirometric Reference Values From a Sample of the United States General Population (Am J. Resp. Crit. Care Med 1999, 159: 179-187) which clearly shows separate predicted values for various ethnic groups. I then personally contacted Dr. Hankinson who confirmed that his work provides distinct reference values for the major American ethnic groups (Caucasian, African-American, Mexican-American), and volunteered to serve as a consultant to this project (Exhibit #29).

It should be noted that most plaintiffs experts and their laboratories appear to follow ATS recommendations on this matter. The lack of a uniform policy makes it extremely difficult to assess any given PFT without recalculating the predicted values on each individual case. Further, because of the frequency of impairment when ATS criteria are not followed, this fact alone can significantly affect the number of cases deemed to be future impaired nonmalignant cases. It may be viewed as "penalizing" those who follow ATS recommendation on this issue.

Comment on ethnicity: Owens Corning requested that this issue not be quantified and that it not be used to formulate my final opinions in this study. Accordingly, the issue has been reported, but is not reflected in the computations to determine impairment.

4) Height - ATS recognized the importance of height in computing predicted values. Errors in both under and over-reporting of height were noted (Exhibit #30).

A female with a height reported at 85" (7 feet, 1 inch) was not challenged by the PFT lab or 2 plaintiff experts who subsequently issued reports on plaintiff Hilda Alexander.

Mr. Billy Stewart was reported at 56" (4 feet, 8 inches) with a weight of 180 pounds resulting in an FVC of 176% of predicted. This was performed by Health Screen, Inc., of Jackson, Mississippi. HealthScreen, Inc. accounted for at least 102 of the PFTs which were performed (Exhibit #31).

Industrial Health Council (IHC)

1) Total Lung Capacity (Exhibit #19)

The Agreements rely largely on spirometry for a claimant to qualify as a nonmalignant impaired. However, an alternative method for qualification for compensation under Appendix "A" is a reduced Total Lung Capacity (TLC). I noted a significant number of cases which failed to qualify because of normal FVC or reduced FEV1/FVC ratio airway obstruction but appeared to qualify based on a low TLC. Further investigation revealed that neither a residual volume (RV) or functional residual capacity (FRC) could be identified in the study.

I telephoned Industrial Health Council and spoke with their technician and learned the studies had been performed on a piece of equipment called a SpiroLab manufactured by Spirometrics. Neither Ms. Jones(technician) nor her supervisor could explain how the PFT equipment generated the TLC other than to state they pressed a button entitled "TLC". We requested a printout of RV or FRC and they found that their lab could not produce that information. A subsequent call to the manufacturer (Spirometrics) initially yielded little further information. Ultimately, I spoke with a Mr. Ballentine in Research & Development who confirmed that the Spirolab lacked a module to measure TLC and never should have been marketed for that purpose. The equipment took the alveolar volume (VA) from the diffusion capacity study and relabeled it as TLC. Where airway obstruction is present this will underestimate the TLC by up to 30%.

Compounding this problem was the fact that not all DLCO measurements were performed according to ATS standards.

Because of all the above, in most instances, I elected to disregard the TLC generated by the IHC Lab. The only cases in which it might be considered were a few cases where the FVC was marginal on a valid spirometry in the absence of airway obstruction and where the DLCO met ATS performance criteria.

Copies of notes of conversations, communication and examples of the PFTs are contained in (Exhibit #19).

2) **DLCO** - difficulties were encountered with DLCOs with breathhold times not being routinely reported and inadequate IVC (did not equal 90% of FVC). Copies of the manual defining the performance of the DLCO was provided to us by Industrial Health Council on request. Their technician, Star Jones, acknowledged that some of the DLCOs did not meet ATS criteria and should have been repeated (Exhibit #19).

3) **Predicted Values** . - IHC uses Knudson; The predicted values appear accurate for Caucasians but do not appear correct for Blacks (Exhibit #32).

Industrial Health Council (IHC) performed at least 157 of the PFTs (Exhibit #33). Attention should be paid to the comment section on Exhibit #33 which documents the disproportionate reduction in TLC.

Respiratory Testing Services (RTS) (Exhibit #34)

Patient Effort and Test Performance

1) In some cases, only one effort is presented and on some cases there is poor patient effort or cooperation (Exhibit #36). Exhalation time of 2 seconds is noted.

2) Back extrapolation and variable effort was common (Exhibit #37).

3) Where ethnicity, sex, height age and weight are identified, it does not appear that predicted values are corrected in accordance with ATS standards. By example, Louis Walker, age 39, was considered to be 69% of predicted, but when using the appropriate Morris or Crapo values, he is 82% of predicted. Sylvester Thirkell, age 47, has a predicted value of 72% for FVC. While using the appropriate Morris or Crapo predicted values, the value would be 84%. Earl M. Brooks using the RTS predicted values was 67% for FVC, while using Morris/Crapo he was 80%. Numerous other examples are available. There appears to be at least a 12-13% difference between the predicted values utilized by RTS and those which would be utilized under ATS Guidelines.

4) There appear to be two different laboratories using the name **Respiratory Testing Services**. In 1994 (Clinton Bowman - example, [Exhibits #35$]), Respiratory Testing Services was located at 404 Fourth Ave., Bessemer, AL.

A company using the name, Respiratory Testing Services in Mobile, AL., (address unknown), appears to be utilizing different equipment in November 1996 (Alfred Thomas and Albert McMillan - examples [Exhibit #35]). The latter studies as a rule appear to be of better quality in 1996 than the earlier studies performed in 1994. This situation and timing is similar to the apparent disappearance of Pulmonary Testing Services and appearance of the "No Name" laboratory.

Respiratory Testing Service while appearing to have certain reproducible studies had pulmonary function tests provided which did not include the patient's age, race, height, sex or other information. Examples included are those of Mr. Alfred Thomas, SSN 423-30-93 17 and Albert McMillan (Exhibit #35). There was no demographic data provided, BTPS or other information. It is possible these PFTs had other pages which were not provided.

Respiratory Testing Services performed at least 113 PFTs (Exhibit #34). The comment section identifies to some extent the frequency with which poor effort and back extrapolation were noted. The failure to provide evidence of 3 patient efforts was also a fairly frequent occurrence.

Pulmonary Function Laboratory in Charlottesville, Virginia-utilized by Dr. R.C. Bernstein

An unusually high percentage of pulmonary function results produced by this laboratory appeared to have significantly lower values when compared with prior pulmonary functions which had been performed on the same plaintiff at different laboratories (Exhibit #38).

Patient #1 - Larry M. Millner - SSN 225-54-4444

Age 55, original PFT tested by Dr. Gaziano on 10-30-97. FVC 3.61 liters, 106% predicted. Patient height 65 inches. The test by Dr. R.C. Bernstein in Charlottesville, VA., 4-6-99, age 57, height 65 inches, FVC 2.59 liters, 64% predicted. In an 18 month period the FVC dropped by greater than one liter and dropped from 106% to 64%. Flow volume loop shows a possible cough artifact.

Patient #2- Thomas McGraw - SSN 227-16-0817 (OC No 10903)

Patient initially tested by Dr. Gaziano on 9-22-94. FVC 3 liters, 93% predicted. TLC 5.22 liters, 97% predicted. 63 inches. Retest by Dr. Bernstein on April 14, 1999, FVC 2.36 liters, 69% predicted. TLC 4.79 liters, 81% predicted. Height was 64 inches. In five years, Mr. Thomas lost approximately 900 ccs of FVC, declined from 93% to 69% predicted and grew one inch in height. Despite aging 5 years, the FVC predicted increased from 3.23 to 3.44.

Patient # 3 - Wendell Ritter - tested on 10-15-94 by Dr. Gaziano. Height was 68 inches, FVC 2.89 liters, 66% predicted. Retested in 1999. FVC 2.83 liters, 60% predicted. Height was 70 inches. In 1994 the predicted value was 4.4 liters per Gaziano. In 1999 the predicted value was 4.7 liters by Dr. Bernstein. During this 5 year period, the predicted values should have fallen instead of risen. Difference is explained by unexplained 2 inch increase in height. Also no bronchodilator is given despite FEV1/FVC .63%.

Patient #4- Simerley Worley - .tested on March 1, 1996 by Dr. Gaziano. Height was 68 inches, FVC 3.97 liters, 88% predicted. TLC is 6.67 liters, 101% predicted. Retested by Dr. Bernstein on April 12, 1999. FVC was 2.71 liters (58% predicted). TLC was 3.99 liters, 59% predicted. Height was 69 inches. The predicted value for FVC had increased to 4.67 from 4.53 despite the fact that the individual had aged by three years. Height increased by one inch. FVC dropped from 88% to 58% predicted and TLC dropped from 101% to 59% predicted. It is believed that both entities are using Crapo for predicted. The curves generated by Dr. Bernstein appear to be reproducible, but show a cough artifact on the flow volume loop.

Patient #5 - Maynard Thompson, SSN 228-28-1219 .originally tested on 4-24-96. FVC was 4.45 liters, 93% predicted. TLC 7 liters, 95% predicted. Height was 72 inches. Retested on 4-6-99 approximately 3 years later. Height was 73 inches, FVC was 4.07 liters, TLC 6.59 liters, 87% predicted. In three years the FVC dropped by 400 ccs and dropped from 93% to 81% of predicted. The predicted values actually increased from those used by Dr. Gaziano in 1996 at 4.8 liters to a predicted value of 5.0 liters for FVC in 1999 despite the fact that the patient was aging. The TLC dropped from 7 liters (95%) to 6.59 liters (87%). The predicted values of the TLC actually rose 7.39 to 7.59 despite the patient aging by three years.

There are handwritten alterations (not explained) on some studies.

These PFTs on the surface appear to be reproducible. Part of the anomaly can be explained by the fact that individuals measured for height in the Bernstein laboratory appear taller than in other laboratories on studies performed in previous years. Typically with aging height diminishes. The result of an increase in height would be a lower percent of predicted and an increased incidence of impairment. Also of concern is the apparent decline in absolute measurement in FVC - greater than would be expected by aging alone and unexplained by any clinical information which is provided. At this time, the reason for these changes is unclear. Possible explanations would include progression of disease, new unexplained clinical phenomena, problems with calibration with equipment in the Bernstein lab or other potential problems with the hardware. Retest of some patients evaluated by Dr. Bernstein may be warranted.

DLCO - St. Vincents Hospital - Birmingham

Significant errors were noted on the diffusion capacity and spirometry. Because of these problems I called Mr. Lee in the Pulmonary Function Lab at St. Vincents (Exhibit #39):

- 1) Problems with identifying breath hold time
- 2) Numerous problems with the curves
- 3) The hospital's computer identified numerous error codes and specifically stated studies had not met ATS criteria
- 4) This technician who also was the laboratory director could not identify the meaning of any of the error codes.
- 5) The technician who performed the studies and also served as director of the laboratory was unable to answer certain questions concerning test performance and why the study was not repeated.
- 6) Problems with the column in the DLCO equipment existed
- 7) These studies were released by the hospital without any physician review. Mr. Lee stated that when he agreed to perform these studies at the request of an attorney, that "no pulmonologist in the hospital would touch them" and thus, they were not reviewed. Notes from this telephone conversation are included

(Exhibit #3 9).